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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-20-0576]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled Possession, Use, and Transfer of Select Agents and Toxins to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on April 3, 2020 to obtain comments from the public and affected agencies. CDC received one comment related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

- (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of

the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the

Attention: CDC Desk Officer, Office of Management and Budget, 725  
17th Street, NW, Washington, DC 20503 or by fax to (202) 395-5806.  
Provide written comments within 30 days of notice publication.

#### Proposed Project

Possession, Use, and Transfer of Select Agents and Toxins (OMB  
Control No. 0920-0576, Exp. 10/31/2020) - Revision - Center for  
Preparedness and Response (CPR), Centers for Disease Control and  
Prevention (CDC).

#### Background and Brief Description

Subtitle A of the Public Health Security and Bioterrorism  
Preparedness and Response Act of 2002, (42 U.S.C. 262a),  
requires the United States Department of Health and Human  
Services (HHS) to regulate the possession, use, and transfer of  
biological agents or toxins that have the potential to pose a  
severe threat to public health and safety (select agents and  
toxins). Subtitle B of the Public Health Security and  
Bioterrorism Preparedness and Response Act of 2002 (which may be  
cited as the Agricultural Bioterrorism Protection Act of 2002),  
(7 U.S.C. 8401), requires the United States Department of  
Agriculture (USDA) to regulate the possession, use, and transfer  
of biological agents or toxins that have the potential to pose a  
severe threat to animal or plant health, or animal or plant

products (select agents and toxins). Accordingly, HHS and USDA have promulgated regulations requiring individuals or entities that possess, use, or transfer select agents and toxins to register with the CDC or the Animal and Plant Health Inspection Service (APHIS). See 42 CFR part 73, 7 CFR part 331, and 9 CFR part 121 (the select agent regulations). The Federal Select Agent Program (FSAP) is the collaboration of the CDC, Division of Select Agents and Toxins (DSAT) and the APHIS Agriculture Select Agent Services (AgSAS) to administer the select agent regulations in a manner to minimize the administrative burden on persons subject to the select agent regulations. The FSAP administers the select agents regulations in close coordination with the Federal Bureau of Investigation's Criminal Justice Information Services (CJIS). Accordingly, CDC and APHIS have adopted an identical system to collect information for the possession, use, and transfer of select agents and toxins.

CDC is requesting OMB approval to continue to collect information under the select agent regulations through the use of five forms: 1) Application for Registration for Possession, Use, and Transfer of Select Agents and Toxins (APHIS/CDC Form 1); 2) Request to Transfer Select Agents or Toxins (APHIS/CDC Form 2); 3) Incident Notification and Reporting (Theft, Loss, or Release) (APHIS/CDC Form 3); 4) Reporting the Identification of a Select Agent or Toxin (APHIS/CDC Form 4); and 5) Request for

Exemption of Select Agents and Toxins for an Investigational Product (APHIS/CDC Form 5).

An entity may amend its registration (42 CFR 73.7(h)(1)) if any changes occur to the information previously submitted to CDC. When applying for an amendment to a certificate of registration, an entity would complete the relevant portion of the application package (APHIS/CDC Form 1).

Besides the forms listed above, there is no standard form for the following information:

1. An individual or entity may request an exclusion from the requirements of the select agent regulations of an attenuated strain of a select agent or a select toxin modified to be less potent or toxic. (42 CFR 73.3(e) and 73.4(e)).
2. Annual inspections that are conducted by the entity must be documented. (42 CFR 73.9(a)(6)).
3. An individual's security risk assessment may be expedited upon written request by a Responsible Official and a showing of good cause. (42 CFR 73.10(f)).
4. An individual or entity may request approval to perform a "restricted experiment" (42 CFR 73.13).
5. An individual or entity must develop and implement a written security plan, biosafety plan, and incident response plan (42 CFR 73.11(a), 42 CFR 73.12(a), and 42 CFR 73.14(a)).

6. The Responsible Official at the entity must ensure a record of the training for each individual with access to select agents and toxins and each escorted individual is maintained (42 CFR 73.15(d)).

7. An individual or entity may appeal a denial, revocation, or suspension of registration. (42 CFR 73.20(a)).

8. An individual may appeal a denial, limitation, or revocation of access approval. (42 CFR 73.20(b)).

The total estimated annualized burden for all data collection was calculated using the 2018 Annual Report of the Federal Select Agent Program available at <https://www.selectagents.gov/annualreport2018.html> or FSAP IT system and is estimated as 4467 hours. Information will be collected through FSAP IT system, fax, email and hard copy mail from respondents. Upon OMB approval, CDC will begin use of the revised forms in October 2020 through October 2023. There is no cost to the respondents.

Estimated Annualized Burden Hours

Section	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)
Sections 3 & 4	Request for Exclusions	1	1	1
Sections 5 & 6	Report of Identification of a Select Agent or Toxin	1,181	1	1
Sections 5 & 6	Request of Exemption	1	1	1
Section 7	Application for Registration	3	1	5
Section 7	Amendment to a Certificate of Registration	253	5	1
Section 9	Documentation of self-inspection	253	1	1
Section 10	Request for Expedited Review	1	1	0.5
Section 11	Security Plan	253	1	1

Section 12	Biosafety Plan	253	1	1
Section 13	Request Regarding a Restricted Experiment	1	1	2
Section 14	Incident Response Plan	253	1	1
Section 15	Training	253	1	1
Section 16	Request to Transfer Select Agents and Toxins	253	1	1.5
Section 17	Records	253	1	0.5
Section 19	Notification of Theft, Loss, or Release	201	1	1
Section 20	Administrative Review	28	1	1

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